IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* AMY BERGMAN, *et al*., Plaintiffs, v. ABBOTT LABORATORIES, Defendant.	Civil Action No. 09-4264 (CDJ)

RESPONSE IN OPPOSITION TO RELATOR'S MOTION TO COMPEL ANSWERS TO RELATOR'S FIRST AND SECOND SET OF REQUESTS FOR PRODUCTION TO DEFENDANT ABBOTT LABORATORIES

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INTRODUCTION

In her latest motion to compel—the fourth such motion filed in the last six weeks—Relator moves the Court to compel responses to her 295 Requests for Production ("RFPs") despite the fact that she has yet to provide substantive responses to proposed compromises on custodians, date ranges, and search terms that Abbott provided weeks, even months, ago. Abbott has repeatedly asked Relator to come to the table and discuss its proposals, but has been met with unilateral declarations that negotiations are over, and serial motions to compel.

Relator's refusal to agree on, or even discuss, reasonable parameters for collecting and producing documents—despite Abbott's willingness to collect documents for dozens of custodians spanning, in many instances, a decade or more—is coupled with an insistence on receiving vast swathes of irrelevant and overly burdensome discovery completely untethered from the claims at issue in this case, which are related to alleged False Claims Act liability in connection with the promotion of the drug TriCor and alleged improper inducements to physicians to prescribe TriCor. Yet Relator has issued literally dozens of RFPs relating to other drugs, including, for example, at least 9 RFPs relating to Certriad—a product that was never approved, marketed, or sold. Numerous other requests are explicitly worded to include ***any*** cholesterol drug, whether or not Abbott marketed or sold it. Relator also seeks wholly irrelevant materials relating to adverse event reports and physician complaints about the efficacy of TriCor and other drugs even though these issues are entirely unrelated to her claims in the case.

Faced with Relator's amorphous mass of RFPs and her unrealistic, uncompromising positions on nearly every issue relating to document collection and production, Abbott has repeatedly attempted to negotiate with Relator while taking what steps it can to move forward in the absence of meaningful cooperation from the requesting party. These steps include:

- Production of over ***38,000*** of the most relevant documents in the case, consisting of nearly 300,000 pages, comprising every single document requested by the federal government and produced by Abbott in connection with the federal investigation of Relator's allegations;

- Production of ***2.9 million*** call note database entries reflecting sales interactions with physicians containing search terms ***specified by Relator***;

- Production of estimates regarding the amount of sales attributable to relevant government reimbursement channels, including Medicare Part D, Medicaid, VA, Department of Defense, and the Public Health Service;

- Collection of hundreds of megabytes of data—including some that had to be extracted from inactive databases—documenting individual TriCor prescriptions on a prescriber-by-prescriber basis for 2003-2008; as well as

- Collection of (to date) over a million of custodial documents (including e-mail, hard drive, and other files) for custodians as to whom the parties do not appear to have a substantive disagreement, so that review and production can commence promptly ***if and when*** Relator agrees to discuss the time frame for production and the search terms to be used in identifying potentially relevant materials.

Relator's claims that she is being stonewalled are simply not supported by the record. Instead, she has shut down discussions regarding the practicalities of document collection and production and has insisted on fighting for ever-broadening date ranges for production and tangential distractions instead of reaching agreement on core, relevant materials. Relator's positions are unsupported by the law and in direct opposition to the spirit of reasonableness and compromise underlying the Federal and Local Rules. Therefore, her motion should be denied.

BACKGROUND

A. Relator's RFPs

Relator's claims in this case are based on the federal False Claims Act ("FCA") and state-law analogs. The crux of each claim is that Abbott, through its marketing of TriCor, "caused" the submission of TriCor reimbursement claims that were "false" because they were not

reimbursable and should not have been paid.[1] Relator's RFPs, however, address numerous topics that have little or nothing to do with Relator's claims, including, among others:

- documents relating to the drugs TriLipix and Certriad (neither of which was marketed concurrently with TriCor; indeed, Certriad was never marketed at all);[2]
- documents relating to adverse events, post-marketing reports and physician complaints involving the safety of TriCor and other drugs;[3] and
- prescribing data and other information relating to any and all "lipid regulating drugs" (not limited to TriCor, and not even limited to drugs Abbott manufactured or sold).[4]

Furthermore, although the Court has ruled that Relator's FCA claims are barred before September 18, 2003, Relator's RFPs define the relevant period for discovery as January 1, 2000 to present. Incredibly, in subsequent correspondence, Relator has taken the position that the generally-applicable discovery period should actually be broader—January 1, 1997 to present—and has demanded discovery covering that time period for at least 137 of her 295 RFPs.

Relator's RFPs are also filled with vague, undefined terminology. Relator uses her own medical jargon, such as "first-line treatment for diabetic patients" (RFP 28), and uses phrases like "pharmacy and pharmacist resistance" (RFP 82), "marketability matrix criteria" (RFP 116), "under Abbott's umbrella" (RFP 191) and "impact of the use or prescribing of TriCor" (RFP 242) with no definition of what these terms mean. Abbott objected to these and many other unduly vague terms in responding to Relator's RFPs.

B. Abbott's Previous Production of Documents

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[1] As Relator puts it, her claim is "that Abbott caused the submission of numerous false claims to government health care programs through its illegal off-label marketing and kickback scheme for TriCor." (Br. at 3 (Dkt. 117-5))

[2] *See, e.g.*, RFPs 7, 8, 9, 10, 11, 51, 52, 53, 57, 58, 81, 107, 137, 149, 150, 153, 157, 159, 160, 161, 162, 165, 166, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 195, 217, 225, 226, 231, 235, 236, 237, 239, 246, and 247.

[3] RFPs 233, 234, 235, 236, 237, 238, and 239.

[4] RFPs 74, 75, 76, 77, 81, 101, 116, 118, 119, 140, and 141.

Relator specifically requested in RFP 150 every document that Abbott provided to the federal government in response to its investigation of Relator's sealed *qui tam* complaint. The same set of documents contain documents responsive to Relator's numerous requests relating to Abbott's organizational structure, marketing plans, promotional messaging, and interactions with physicians, among others.[5] The parties agreed to prioritize these requests and specifically agreed that Abbott would produce the entirety of its government production as well as entries from its database of call notes (specifically requested in RFPs 77-80) containing search terms provided by Relator. On September 29, 2014 Abbott produced 38,672 documents spanning almost 300,000 pages, plus over 2.9 million call note entries in a searchable database.[6]

C. Relator's Delays and Refusal to Negotiate in Good Faith

Relator's numerous, often months-long, delays in responding to meet-and-confer proposals, culminating in a unilateral declaration of an "impasse" and refusal to negotiate, are thoroughly documented in Abbott's Response to Relator's Motion to Compel Answers to Relator's Interrogatories. (Dkt. 116) Because Relator's recently-filed multiple motions are being addressed simultaneously, Abbott will not reiterate those facts here.

ARGUMENT

A. Relator's Refusal to Discuss Custodians or Search Terms is Impeding Discovery

Simply put, there is no feasible way for Abbott to produce documents in response to Relator's RFPs in the absence of (a) a defined set of custodians from whom to collect; (b) a

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[5] The materials are, at a minimum, responsive to RFPs 1, 4, 5, 6, 11, 12, 13, 14, 15, 16, 17, 18, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 49, 50, 54, 64, 65, 66, 67, 68, 69, 70, 71, 72 and 73.

[6] *See* Declaration of Jonathan R. Lahn ("Lahn Decl."), Ex. 1 (filed herewith). Relator asserts in her motion, with no support, that the parties "specifically agreed" that this production would not be used in connection with any future discovery dispute. Abbott is not using the production to argue that Relator has waived her right to more discovery. Abbott is merely pointing out that Relator's repeated statements that "no" documents have been provided in response to her RFPs are patently false.

known date range; and (c) search terms to identify potentially responsive documents. Despite Relator's typically heated rhetoric, this is not a "specious" or "duplicitous" argument but simply a practical reality. Relator's extremely broad requests cover every facet of pharmaceutical marketing and decades of time. It is simply not feasible for Abbott to respond to these requests other than by identifying and agreeing with Relator on a reasonable list of custodians likely to possess responsive documents, collecting documents from those custodians, and using search terms to filter the millions of resulting documents to those that are potentially responsive.

Relator's motion attacks the very concept of custodian lists and the use of search terms to identify potentially relevant documents. (Br. at 5) Needless to say, identifying custodians and collecting documents from them is a widely-accepted practice in federal litigation. *See, e.g.*, The Sedona Conference Cooperation Proclamation: Resources for the Judiciary (August 2011) at 21[7] ("One goal of judicial case management should be to encourage parties to agree on a search and collection methodology before discovery begins. . . . Defining such a methodology in terms of date ranges, data sources, and custodians enables parties to conduct e-discovery in an efficient and cost effective way"). So is the use of search terms, which requires "careful thought, quality control, testing, ***and cooperation with opposing counsel*** in designing search terms or 'keywords' to be used to produce emails or other electronically stored information" to narrow the pool of potentially relevant documents. *National Day Laborer Org. Network v. United States Immigration and Customs Enforcement Agency*, 877 F. Supp. 2d 87, 109 (S.D.N.Y. 2012) (emphasis added). Search terms are particularly important where, as in this case, there are millions of documents at issue.

[7] Available on the Federal Judicial Center website at http://www.fjc.gov/public/pdf.nsf/lookup/SedonaRes.pdf/$file/SedonaRes.pdf.

There is nothing "arbitrary" about Abbott's proposed custodian lists. Abbott specifically provided Relator with the roles and titles of each proposed custodian. (*See* Lahn Decl. Ex. 2) Moreover, Relator has had 38,641 relevant documents since September, including organizational charts, to inform her own determinations of who the relevant custodians are. In fact, Relator formulated her ***own*** proposed custodian list on April 3, 2015 (albeit an over-inclusive one), which even contained the titles and roles of additional custodians, undercutting her claim that she lacks sufficient information to evaluate who the relevant custodians should be. (*See* Lahn Decl. Ex. 4)

Abbott's April 13 proposed custodian list was based on Relator's original, over-inclusive list, and was specifically annotated to explain why Abbott believes certain custodians should be included or removed. (*See* Lahn Decl. Ex. 5) In the absence of agreement, and indeed any response, from Relator, Abbott has proceeded to collect and process documents from those custodians on Relator's list that Abbott also included on its proposed list. However, Abbott cannot move forward in processing and reviewing the documents for production without some agreement from Relator on the relevant date range and search terms to be used in identifying documents for review. Indeed, the sheer volume of documents collected thus far—in excess of a million documents—further underscores the need for parameters to focus the search and review on materials that may actually be relevant to Relator's claims.

B. Abbott's Relevance Objections Are Proper

While broad, the scope of discovery under the Federal Rules "is not unlimited." *Bayer AG v. Betachem, Inc.*, 173 F.3d 188, 191 (3rd Cir. 1999). To be discoverable, materials must be "reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(2). Moreover, Rule 26(b)(1), in defining the scope of discovery, expressly emphasizes that

discovery should be "proportional to the needs of the case," including taking into account the burden of providing the requested discovery in comparison to the likely value of the information obtained.

1. Temporal Scope

The Court has already ruled that Relator's False Claims Act claims are barred prior to September 18, 2003. Abbott's promotion of TriCor (and thus any alleged causation of the submission of false claims) ended in December 2008, a fact that is reflected in documents Abbott has produced and specifically identified to Relator. Therefore, Abbott initially proposed that discovery should be limited to the period September 2003 through December 2008. In response to Relator's argument that she is entitled to documents relating to a reasonable period preceding the limitations period, Abbott proposed that discovery be extended to the period January 2002 through December 2008—an extra 21 months. (*See* Lahn Decl. Ex. 3) Abbott then agreed, in response to further demands from Relator, to provide discovery from 1997 through 2001 and 2009 to present in response to several dozen RFPs identified by Relator (though admittedly not all of the 137 RFPs she demanded). (*See* Lahn Decl. Ex. 6)

Relator simply cannot justify forcing Abbott to produce documents for every RFP, or even 137 RFPs, for the entire 1997-2015 time period in a case where her actionable claims lie between September 2003 and December 2008. Indeed, Relator barely attempts to provide justification, simply asserting in a few sentences that TriCor's label changes, communications with the FDA, and internal discussions of what is "off-label" are "key issues" that "patently predate" 2002. (Br. at 7-8) She makes no effort to tie these allegedly "key" issues to her actual claim that Abbott caused the submission of non-reimbursable claims for TriCor between 2003 and 2008. Furthermore, almost all of these topics are topics as to which Abbott agreed to

provide expanded discovery on May 21, 2015, before Relator's unilateral decision to end discussions.

2. Substantive Scope

It is telling that Relator accuses Abbott of making "improper" relevance objections to her RFPs, but chooses not to discuss any of the actual topics of those RFPs, save one. Among the irrelevant topics covered by her RFPs that she does ***not*** discuss are nine different requests relating to a drug that was never produced or marketed, requests regarding adverse events and safety complaints (even though the safety of TriCor is not at issue in her claims), and requests that apply to all cholesterol drugs, even those that Abbott did not market or produce. Relator does not even attempt to defend the relevance of these requests.

The one category that Relator actually discusses is RFPs related to TriLipix, a drug approved by the FDA at the end of 2008, at the same time that TriCor ceased to be promoted. Relator does not deny that she asserts no claims based on the promotion or reimbursement of TriLipix. Rather, she argues that the messages Abbott used to promote TriLipix somehow show that Abbott's prior claims about TriCor were false or misleading. (Br. at 9) Conveniently, extending discovery to TriLipix also allows Relator to claim that she needs discovery from 2009 to present, since TriCor ceased to be promoted in December 2008. Relator's argument is misleading at best, since it suggests that the only materials she seeks regarding TriLipix are marketing materials that reflect on TriCor. That is not at all the case. Instead, Relator seeks a plethora of non-marketing-related documents involving TriLipix, including all FDA correspondence (RFPs 8, 149, 160, 165 and 166); internal analyses of TriLipix' label and reports/complaints regarding its safety (RFPs 181, 182, 195, 219, 231, 235, and 236); and financial analyses, sales projections, sales goals and actual sales (RFPs 136, 246, and 247).

Furthermore, even documents relating to the marketing of TriLipix are irrelevant. Aside from vague statements about how the drugs were "related" and part of a "comprehensive strategy" Relator does not articulate any reason why the marketing of TriLipix in 2009 and beyond retroactively renders the alleged causation of false claims for TriCor from September 2003 through December 2008 more or less probable.

C. Abbott's Vagueness Objections Are Proper

Relator attacks Abbott's vagueness objections as being "beyond disingenuous" and "not grounded in good faith" in a single paragraph and provides no explanation with respect to particular terms. (Br. at 10) Nor does she identify particular RFPs at issue. Rather, she simply lists some terms and asserts that they are "basic industry and commonly utilized terms" whose meaning is clearly based on "reason and common sense." (*Id.*) Abbott respectfully submits that undefined phrases like "first-line treatment for diabetic patients," "physician and pharmacy resistance," "marketability matrix criteria," "under Abbott's umbrella" are not at all clear, particularly in the context of Relator's RFPs.

D. Abbott's General Objections Are Still Proper

Relator raises the issue of general objection here for at least the third time in as many motions, using the same language and citing the same case.[8] In the interest of efficiency Abbott incorporates the arguments set forth in its responses to Relator's prior motions (*see* Dkt. 107 at 5-6; Dkt. 116 at 10) and notes that it agreed to produce documents subject to those objections.

E. Relator's Argument Regarding Contractual Obligations is Cynical and Silly

Relator's argument that Abbott has wrongfully withheld relevant discovery based on contractual confidentiality obligations to third parties is an example of her willingness to use any

[8] Relator's attack on general objection is also included in her motions to compel regarding Abbott's RFA responses and Abbott's interrogatory responses.

possible basis to attack Abbott and her lack of candor to the Court. Relator claims that she does not know what contract is at issue. This is false. Relator has had multiple discussions with Abbott dating back to at least October 2014 discussing the fact that Abbott's contract with IMS Health Services prohibits Abbott from producing data purchased from IMS without prior approval. In fact, Relator, who has purchased her own IMS data, has used ***the same*** contractual limitation to justify her own failure to produce that data to Abbott.[9] Her counsel has even asked Abbott to help her identify the person she needs to talk to at IMS,[10] and pledged, as recently as Tuesday, June 23 (four days after this motion was filed) that she was in discussions with IMS regarding the same contractual provision.[11]

CONCLUSION

Abbott has repeatedly made significant concessions and stands prepared to produce years' worth of documents for dozens of relevant custodians if Relator will simply agree to reasonable parameters, including a date range, a custodian list, and search terms—items that are standard procedure in modern civil litigation. The status of document production in this case is a reflection of Relator's refusal to engage in discussions on these topics. Relator's legal arguments are without merit, and Abbott respectfully submits that Relators motion should be denied.

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[9] (*See* Lahn Decl. Ex. 7) ("The IMS data was not included in the production. We will have to check with IMS as to whether we can share that data with you. As you are aware, IMS purchase agreements restrict a purchaser's ability to share the data; a fact that Abbott has raised several times with us to explain why Abbott has not yet produce [sic] the IMS data it possesses to us for the last 8 or 9 months.").

[10] (*See id.*) ("Perhaps you can tell us who at IMS your firm has been dealing with in trying to get permission to share Abbott's IMS data with us and we can go to the same person and hopefully get a more efficient process going.").

[11] (*See* Lahn Decl. Ex. 8) ("The IMS contract person we dealt with is awaiting a response from IMS legal regarding the disclosure of the data to you."). Moreover, as of June 26, both parties have received the necessary permissions, rendering this point moot.

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